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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/928,464	08/13/2001	William J. Boyle	ACS-57080	6454

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EXAMINER

THOMPSON, KATHRYN L

ART UNIT PAPER NUMBER

3763

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/928,464

Applicant(s)

BOYLE ET AL.

Examiner

Kathryn L Thompson

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) 6,9-14,16,17,21-28,30 and 36-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7, 8, 15, 18-20, 29, 31-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

## DETAILED ACTION

### *Election/Restrictions*

Per Applicant's request to reconsider claims 2, 7, and 8 as being drawn to the elected species, Examiner examines the aforementioned claims.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 4, 5, 7, 15, 18, 19, 20, 29, 31, 34 are rejected under 35

U.S.C. 102(b) as being anticipated by Schiff (US 4,473,067). Schiff discloses a delivery system comprising a sheath (40), a guide wire (26), a handle (Figures 1-3), a device coupling the sheath to the handle (Figures 1-3), a device configured to split the longitudinal joint and to allow the sheath to be removed (50), a blade (Figure 4a), and a guide mandrel (16).

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 4, 5, 15, 18, 19, 20, 29, 33, 34, and 35 are rejected under 35 U.S.C. 102(e) as being anticipated by Gardeski et al (US 6,159,198). Gardeski et al discloses a delivery system comprising a sheath (10), a guide wire, a handle (62), a device coupling the sheath to the handle (12), a device configured to split the longitudinal joint and to allow the sheath to be removed (60), and the device coupling the proximal portion of the sheath to the distal portion of the handle is split along the length of the device (Column 3, Line 5).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schiff. Schiff does not disclose expressly the shapes of the first side and second side of the longitudinal joint as is claimed in Claim 2. Nor does Schiff disclose expressly that the lumen is capable of being pressurized up to and over 8 atm as is claimed in Claim 8. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to make the shapes of the first and second sides of the longitudinal joint like that of the instant application and making a lumen that is capable of being pressurized up to and over 8 atm because Applicant has not disclosed that making these specific shapes and making a lumen that is capable of

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being pressurized up to and over 8 atm provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with either the teachings of Schiff or the limitations of the instant application. Therefore, it would have been an obvious matter of design choice to modify Schiff to obtain the invention as specified in Claims 2 and 8.

### ***Response to Arguments***

Applicant's arguments filed April 27, 2004 have been fully considered but they are not persuasive. Applicant states that Schiff fails "to disclose a sheath which has a resealable longitudinal joint as recited in claims 1 and 29." Examiner respectfully disagrees. Schiff does indeed disclose a sheath that has a resealable longitudinal joint (Column 10, Lines 3-31).

With regards to Gardeski et al, Applicant states that the "sheath appears to be free of any pre-formed longitudinal joints..." Examiner would like to point out that Applicant does not claim a "pre-formed longitudinal joint." Applicant simply claims a longitudinal joint. As Applicant states himself in the specification of the instant application on Page 14, Lines 18-20, the longitudinal joint can be added later, such as by cutting with a blade or any other means known in the art. Examiner believes that this is exactly what Gardeski et al disclose (adding a joint later).

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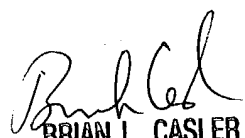
**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn L Thompson whose telephone number is 703-305-3286. The examiner can normally be reached on 8:30 AM - 6:00 PM: 1st Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KLT



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